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Email: sos.information@state.tn.us

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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Board of Pharmacy
Division:	
Contact Person:	Benjamin C. Mezer Assistant General Counsel
Address:	220 Athens Way, Suite 210 Nashville, Tennessee
Zip:	37243
Phone:	(615)741-1611
Email:	Benjamin.mezer@tn.gov

Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables. Please enter only **ONE** Rule Number/RuleTitle per row)

Chapter Number	**Chapter Title**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.01	Definitions
1140-01-.09	Renewal of Licenses
1140-01-.14	Prescription Drugs Dispensed by Health Departments

Chapter Number	**Chapter Title**
1140-02	Professional Conduct and Responsibilities
Rule Number	**Rule Title**
1140-02-.02	Pharmacy Technicians

Rulemaking Hearing Rules
Department of Health
Board of Pharmacy
Division of Health Related Boards

Amendments

Chapter 1140-01
Introductory Rules

Chapter 1140-02
Professional Conduct and Responsibilities

Paragraph (1) of Rule 1140-01-.01 Definitions is amended by deleting the language of the paragraph in its entirety and substituting instead the following:

(1) "ACPE" means the Accreditation Council for Pharmacy Education.

Authority: T.C.A. §63-10-304(b)(1).

Paragraph (3) of Rule 1140-01-.01 Definitions is amended by deleting the language of the paragraph in its entirety and substituting instead the following:

(3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.

Authority: T.C.A. §63-10-304(b)(1).

Paragraph (7) of Rule 1140-01-.01 Definitions is amended by deleting the language of the paragraph in its entirety by substituting instead the following:

(7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.

Authority: T.C.A. §63-10-304(b)(1).

Paragraph (2) of Rule 1140-01-.09 Renewal of Licenses is amended by deleting the paragraph in its entirety and substituting instead the following:

(2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: T.C.A. §63-10-304(b)(1).

Paragraph (4) of Rule 1140-01-.14 Prescription Drugs Dispensed by Health Departments is amended by adding new subparagraphs (o) and (p) as follows:

(o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)

(p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)

Authority: T.C.A. §§63-10-304(b)(1) and 63-10-205.

Paragraph (16) of Rule 1140-02-.01 Pharmacists and Pharmacy Interns is amended by deleting the language of the paragraph in its entirety and substituting instead the following:

(16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the pharmacist's primary practice site, unless it is an institutional pharmacy practice site, in which case, the pharmacist's license and certificate of registration shall be maintained at the site.

Authority: T.C.A. §63-10-304(b)(1) and (c).

Rule 1140-02-.02 Pharmacy Technicians is amended by deleting the language of the rule in its entirety and substituting instead the following:

1140-02-.02 Pharmacy Technicians.

(1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:

(a) Provide a statement of good moral character;

(b) Submit an affidavit from his/her employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment);

(c) Submit the appropriate application fee as set in Board of Pharmacy Rule 1140-01-.10.

(2) The following individuals are exempt from registration as a pharmacy technician:

(a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.

(b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.

(3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.

(4) A registered pharmacy technician may, in the presence of and under the supervision of a pharmacist, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.

(5) Certified pharmacy technicians may also:

(a) Receive new or transferred oral medical and prescription orders;

(b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and

(c) Verify the contents of unit dose carts prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.

(6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.

(7) Pharmacy Technician to Pharmacist Ratio

(a) The pharmacy technician to pharmacist ratio shall not exceed 2:1; however the ratio may be increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only if the additional pharmacy technicians are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:

1. the pharmacy technician's experience, skill, knowledge and training; and

2. the workload at the practice site; and

3. detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and

4. justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.

(b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

(8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).

(9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.

(10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.

(11) All registered technicians shall immediately notify the board in writing of any change of address or employer.

(12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.

Authority: T.C.A. §§ 63-10-304(b)(1), (e), and (j) and 63-10-306.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
David Todd Bess, Pharm D.	X				
Sheila Mitchell, Pharm D.	X				
Julie D. Frazier, D.Ph.				X	
Albert Larry Hill, D.Ph.	X				
James R. Mitchell, Jr., D.Ph.				X	
Bettie K. Wilson, D.Ph.	X				
Monica Franklin	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy on September 12, 2007, and is in compliance with the provisions of TCA §4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *May 30, 2007*

Notice published in the Tennessee Administrative Register on: *June 15, 2007*

Rulemaking Hearing(s) Conducted on: (add more dates). *August 28, 2007*

Date: 10/1/09

Signature: Benj C. Mezer

Name of Officer: Benjamin C. Mezer, Esq.

Title of Officer: Assistant General Counsel
Tennessee Department of Health

THEODORA P. WILLIAMS NOTARY PUBLIC AT LARGE DAVIDSON COUNTY, TENN.

Subscribed and sworn to before me on: 10/1/09

Notary Public Signature: Theodora P. Williams

My commission expires on: 11/7/2011

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

12-21-09
Date

Department of State Use Only

Filed with the Department of State on: 12/23/09

Effective on: 3/23/10

Tre Hargett
Secretary of State

RECEIVED
2009 DEC 23 PM 3: 56
SECRETARY OF STATE
PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

(See page following)

PUBLIC HEARING COMMENTS

RULEMAKING HEARING

TENNESSEE BOARD OF PHARMACY

AUGUST 28, 2007

The rulemaking hearing for the Tennessee Board of Pharmacy was called to order at 9:00 a.m., Central Daylight Time, on August 28, 2007 in the Department of Health Conference Center's Poplar Room on the First Floor of the Heritage Place Building in MetroCenter, Nashville, Tennessee. Jerry Kosten presided over the meeting.

Five (5) members of the public attended the rulemaking hearing and two (2) oral comments were received.

Jennifer Dillard, D.Ph. spoke on behalf of Walgreens. Dr. Dillard said that Walgreens supports the absence of any specified or stated working rations of pharmacy technicians to pharmacists. She also stated that Walgreens supported the TPA's written recommendation to add the word "technician" between the words "pharmacy" and "training" in the proposed subparagraph 1140-02-.02(2)(b).

Greg Young spoke on behalf of the College of Pharmacy at David Lipscomb University. Mr. Young said that the proposed subparagraph 1140-02-.02(2)(b) could be interpreted as implying that to be exempt from registration as a pharmacy technician, a student would have to be enrolled in a formal curriculum instead of an individual rotation. Mr. Young asked for the term "training program" to be clarified.

The rulemaking hearing concluded at 9:45 a.m., Central Daylight Time.

Benjamin C. Mezer, Esq.
Assistant General Counsel
Department of Health

10/1/09
Date

Regulatory Flexibility Addendum
Pursuant to Public Chapter 464 of the 105th General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Economic Impact Statement

(1) Type or types of small business subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

The rules affect all pharmacies, pharmacists, and pharmacy technicians regardless of the size of the business.

(2) Identification and estimate of the number of small businesses subject to the proposed rule:

As of December 31, 2006, Tennessee had 21,166 licensees eligible for licensure renewal who are pharmacists, pharmacies, pharmacy technicians, manufacturers/wholesale/distributors, researchers and medical service representatives.

(3) Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

Not only do the proposed amendments which have economic impact on small businesses have no increased or new reporting, recordkeeping and other administrative costs that are required for compliance, the Board believes the proposed amendments will lead to reduced reporting, recordkeeping and other administrative costs.

(4) Statement of the probable effect on impacted small businesses and consumers:

The Board anticipates the proposed rule amendments regarding pharmacy technicians will result in more efficiencies in the workplace as employers will be able to better utilize employees. This may help to hold down expenses which is of obvious benefit to employers and small business owners, but will also benefit consumers by eventually slowing down increases in health care costs.

(5) Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

The Board does not believe there are less burdensome alternatives because the intent of the proposed rule amendments is precisely that.

(6) Comparison of the proposed rule with any federal or state counterparts:

Federal — The Board is not aware of any federal counterparts. Pharmacists and pharmacy technicians are not licensed by the federal government.

State — Boards of Pharmacy in other states have similar technician functions contained in their rules. They have also eliminated working ratios of pharmacist or pharmacy technicians and left that to the discretion of the pharmacist in charge.

(7) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

It is not possible to exempt the impacted small businesses from almost all of the requirements contained in the proposed rule because the impacted small businesses are the Board's licensees. If there were to be an exemption, the proposed rule amendments would have no actual effect.

However, it should be noted that the proposed rule amendments do create an exemption from the licensure display requirements at institutional pharmacy practice sites.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

1140-1-.01 Definitions—The current rule's definition for the acronym "ACPE" is the American Council on Pharmaceutical Education. The new rule's definition for the acronym "ACPE" is the Accreditation Council for Pharmacy Education. Also, the current rule's definition for "certified pharmacy technician" is an individual who is certified by a national or state certification organization whose certification program is approved by the board. The new rule's definition for "certified pharmacy technician" is an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.

1140-1-.09 Renewal of License—The current rule does not include pharmacy technicians as exempt from payment of renewal fees during periods of active military duty. The new rule makes such inclusion.

1140-1-.14 Prescription Drugs Dispensed by Health Departments—The current rule does not include norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®) and etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®) as reproductive health agents approved as not subject to abuse. The new rule makes such inclusion.

1140-2-.01 Pharmacists and Pharmacy Interns—The current rule does not contemplate institutional pharmacies as they pertain to the display of pharmacy licenses. The new rule exempts pharmacists from the display requirement at institutional pharmacy practice sites, in which case, the pharmacist's license and certificate of registration shall be maintained at the site.

1140-2-.02 Pharmacy Technicians—The current rule does not state who is exempt from registration as a pharmacy technician. The new rule exempts probationary employees and students. Also, the current rule contains seventeen (17) functions that a pharmacy technician can perform under appropriate supervision. The new rule instead provides the more general statement that pharmacy technicians may perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-2-.01(13). Finally, the current rule contains specific working ratios of pharmacy technicians to pharmacists that are not to be exceeded. The new rule revises the actual working ratios but also provides a procedure for the pharmacist in charge to request from the Board a modification of the ratio limits.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Authority for these amendments comes from state statutes regarding the practice of pharmacists and pharmacy technicians, T.C.A. §§ 63-10-101, et seq. The Board has rulemaking authority contained in T.C.A. § 63-10-304.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Individuals most directly affected by these rules are all current and future licensees.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

There are no known opinions of the attorney general or any judicial ruling which relate to these rules.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

There is estimated to be no increase or decrease in expenditures and a minimal decrease in expenditures (due to the military exemption for pharmacy technicians) because of these rule amendments.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Dr. Kevin Eidson, Director of the Board of Pharmacy and Benjamin C. Mezer will explain the rules at any scheduled meeting of the committee.

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Dr. Kevin Eidson, Director of the Board of Pharmacy and Benjamin C. Mezer will explain the rules at any scheduled meeting of the committee.

(H) Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Benjamin C. Mezer may be reached at the Department of Health, Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243 (telephone number: (615) 741-1611). Dr. Kevin Eidson may be reached at Plaza One, Suite 240, 220 Athens Way, Nashville, Tennessee 37243 (telephone number: (615) 741-2718).

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-01
INTRODUCTORY RULES

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1140-01-.01 DEFINITIONS.

~~(1) "ACPE" means the American Council on Pharmaceutical Education.~~

(1) "ACPE" means the Accreditation Council for Pharmacy Education.

(2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.

~~(3) "American Council on Pharmaceutical Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for approval of providers of continuing pharmaceutical education.~~

(3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.

(4) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(5) "Blood fraction/component" means that part of blood separated by physical or mechanical means.

(6) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.

~~(7) "Certified pharmacy technician" means an individual who is certified by a national or state certification organization whose certification program is approved by the board.~~

(7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.

(8) "Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.

(Rule 1140-01-.01, continued)

(9) "Contact hour" means any hour of completed continuing pharmaceutical education programming which is:

(a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or

(b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).

(10) "Continuing education unit" means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.

(11) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.

(12) "Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.

(13) "Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.

(14) "Foreign pharmacy graduate" means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.

(15) "Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.

(16) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n):

(a) adult care facility;
(b) assisted living facility;
(c) correctional facility;
(d) developmental disability center;
(e) hospital;
(f) inpatient psychiatric center;
(g) intermediate care facility for the mentally retarded;
(h) mental health facility;
(i) nursing facility;
(j) personal care home;
(k) rehabilitation center;
(l) residential drug or alcohol treatment center;
(m) rest home;
(n) retirement center;
(o) sub-acute care facility; and
(p) university health center.

(17) "Institutional pharmacy practice site" means a pharmacy practice site serving patients within an institutional facility.

(Rule 1140-01-.01, continued)

(18) "Medication order" means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.

(19) "National Association of Boards of Pharmacy (NABP)" means the professional organization that represents the individual state boards of pharmacy.

(20) "Nuclear pharmacy practice site" means a pharmacy practice site providing radiopharmaceutical services.

(21) "Patient counseling" means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.

(22) "Pharmaceutical care" is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.

(23) "Pharmacy internship" is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.

(24) "Pharmacy practice site" means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

(25) "Preceptor" means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.

(26) "Prescription department" means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.

(27) "Quality assurance" means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.

(28) "Radiopharmaceutical service" means, but is not limited to:

(a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;

(b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) the proper and safe storage and distribution of radiopharmaceuticals;

(d) the maintenance of radiopharmaceutical quality assurance;

(e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and

(Rule 1140-01-.01, continued)

(f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.

(29) "Reciprocity" means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.

(30) "Shall" means that compliance is mandatory.

(31) "Third party pharmacy program" means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.

(32) "Third party pharmacy program administrator" means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.

(33) "Unit dose packaging" means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.

Authority: *T.C.A. §63-10-304(b)(1), T.C.A. §§63-10-101, 63-10-102, 6-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-304, 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.*

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of *T.C.A. § 63-10-505(6).*

Authority: *T.C.A. §§63-10-101, 63-10-102, 63-10-202, 63-10-504(b)(1), and 63-10-505(6).* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.

(1) An application for examination for a license as a pharmacist must be completed and received in the office of the board (with the proper application fee) at least forty (40) days prior to the date of the examination.

(2) For the purpose of *T.C.A. § 63-10-506(d),* a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."

(3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under *T.C.A. § 63-10-505*, unless the applicant can show cause why a license should be issued.

3. Comply with the requirements contained in Chapter 1140-9 of the rules of the board.

(4) Representatives of a manufacturer or wholesaler conducting business in the state of Tennessee and who possess and distribute controlled substances shall obtain a controlled substance registration from the board.

(5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

(6) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:

(a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and

(b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

Authority: *T.C.A. §§53-11-301, 53-14-104, 53-14-106, 53-14-107, 56-1-302(b)(1)(2), 63-10-101, 63-10-102(a), 63-10-203, 63-10-204, 63-10-210, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.09 RENEWAL OF LICENSES.

(1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.

~~(2) A pharmacist serving in the uniformed services of the United States shall not be required to pay license renewal fees or complete continuing pharmaceutical education requirements during the pharmacist's period of active duty.~~

(2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: *T.C.A. §63-10-304(b)(1), T.C.A. §§53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.10 FEES.

(1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars ($50.00) plus cost of the examination and materials.

(Rule 1140-01-.12, continued)

(6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.

(7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.

(8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.

(9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: *T.C.A. §§63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.13 STANDARDS FOR MANUFACTURERS AND WHOLESALERS.

No license to operate a new or remodeled manufacturer or wholesaler location within the state of Tennessee, or an existing manufacturer or wholesaler location which changes location or ownership, will be issued unless the manufacturer or wholesaler meets the standards set forth in Chapter 1140-9 of the rules of the board.

Authority: *T.C.A. §§63-10-404(18) and (37), and 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.14 PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.

For purposes of *T.C.A. § 63-10-405*, the following drugs are hereby approved as not subject to abuse:

(1) Tuberculosis Control Agents:

(a) Capreomycin Injection
(b) Cycloserine Capsules
(c) Ethambutol Tablets
(d) Ethionamide Tablets
(e) Isoniazid Tablets
(f) Para-Aminosalicyclate Tablets
(g) Pyrazinamide Tablets
(h) Rifampin Capsules
(i) Streptomycin Injection
(j) Tuberculin Skin Test (Mantoux only)
(k) Rifampin/Isoniazid
(l) Ofloxacin
(m) Rifampin-isoniazid-pyrazinamide

(2) Venereal Disease Control Agents:

(a) Ampicillin Capsules
(b) Doxycycline Capsules
(c) Erythromycin Tablets
(d) Penicillin

(Rule 1140-01-.14, continued)

1. Benzathine Penicillin G Injection
2. Procaine Penicillin G Injection

(e) Probenecid Tablets
(f) Spectinomycin Injection
(g) Tetracycline Capsules
(h) Ceftriaxone
(i) Ciprofloxacin
(j) Lidocaine Injection
(k) Azithromycin
(l) Acyclovir Tablets, Ointments
(m) Trichloroacetic Acid
(n) Salicylic Acid
(o) Podophyllin/Salicylic Acid
(p) Aldara (Imiquimod)

(3) Biologicals/Immunizations:

(a) Antiserums
(b) Antitoxins
(c) Immune Serum Globulin
(d) Toxoids
(e) Vaccines
(f) Antigens

(4) Reproductive Health Agents:

(a) Metronidazole Tablets
(b) Oral Contraceptives
(c) Podophyllin
(d) Prenatal Vitamins
(e) Triple Sulfa Vaginal Cream/Tabs
(f) Vaginal Antifungal Cream/Tabs

1. Clotrimazole
2. Miconazole
3. Nystatin
4. Terconazole (Terazole)

(g) Amino-Cerv
(h) Nitrofurantoin
(i) Ibuprofen, 600 mg Tablets
(j) Metronidazole (vaginal jell)
(k) Fluconazole Tablets
(l) Clindamycin Vaginal Cream
(m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)
(n) Medroxyprogesterone Acetate Injectable (Depo Provera®)
(o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)
(p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)

(5) Child Health Agents:

(a) Fluoride Tablets and Drops
(b) Lindane Cream, Lotion, Shampoo

(Rule 1140-01-.14, continued)

(c) Mebendazole Tablets
(d) Pyrantel Pamoate Liquid
(e) Sulfadiazine Tablets
(f) Trimethoprim and Sulfamethoxazole
(g) Permethrin
(h) Crotamiton
(i) Nystatin Oral Suspension
(j) Nystatin Triamcinolone Cream
(k) Ibuprofen, Suspension Liquid

(6) Emergency Agents:

(a) Aminophylline Injection
(b) Benztropine Injection
(c) Diphenhydramine Injection
(d) Epinephrine Injection
(e) Glucagon Injection
(f) Hydralazine Injection
(g) Hydrocortisone Sodium Succinate
(h) Insulin, Regular
(i) Intravenous Fluids
(j) Oxygen
(k) Phenylephrine Injection
(l) Sodium Bicarbonate Injection
(m) Atropine Injection
(n) Nitroglycerin Sublingual Tablets
(o) Dexamethasone Injection
(p) Norepinephrine

(7) Antihypertensive Agents:

(a) Methyldopa
(b) Reserpine
(c) Hydrochlorothiazide
(d) Hydralazine
(e) Propranolol
(f) Potassium Supplements
(g) Nicotine Patches

Authority: *T.C.A. §§63-10-304(b)(1) and 63-10-205, T.C.A. §§63-10-404(14), 63-10-205, 63-10-304, 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009.*

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-2
PROFESSIONAL CONDUCT AND RESPONSIBILITIES

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1140-2-.01 Pharmacists and Pharmacy Interns 1140-2-.02 Pharmacy Technicians

1140-2-.01 PHARMACISTS AND PHARMACY INTERNS.

(1) A pharmacist shall hold the health and safety of patients to be the first consideration and shall render to each patient the full measure of the pharmacist's ability as an essential health practitioner.

(2) A pharmacist shall not knowingly condone or assist in the dispensing, promoting, or distributing of drugs or devices which are not of good quality, which do not meet standards by law, or which lack therapeutic value for the patient.

(3) A pharmacist shall always strive to perfect and enlarge the pharmacist's professional knowledge and shall utilize and make available this knowledge as may be required in accordance with the pharmacist's best professional judgment.

(4) A pharmacist shall observe the law, uphold the dignity and honor of the profession, and accept its ethical principles. A pharmacist shall not engage in any activity that will bring discredit to the profession, and shall expose, without fear or favor, illegal or unethical conduct in the profession.

(5) A pharmacist shall seek at all times only fair and reasonable remuneration for the pharmacist's services. A pharmacist shall never agree to or participate in transactions with practitioners of other health professions or any other person under which fees are divided, or which may cause financial or other exploitation in connection with the rendering of the pharmacist's professional services.

(6) A pharmacist shall respect the confidential and personal nature of professional and patient records. Except where the best interest of a patient requires or the law demands, a pharmacist shall not disclose such information to anyone without proper patient authorization.

(7) A pharmacist shall not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which tend to cause a deterioration of the quality of professional service and patient care, or which require the pharmacist to consent to unethical conduct.

(8) A pharmacist shall not make publication or circulation of any statement tending to deceive, misrepresent, or mislead anyone, nor be a party or accessory to any fraudulent or deceptive practice or transaction in pharmacy.

(9) A pharmacist shall not enter into any agreement with anyone for the compounding of secret formula or coded medical or prescription orders.

(10) A pharmacist shall, by utilizing education, skill, experience, and professional judgment, make every reasonable effort to prevent the abuse of drugs which the pharmacist dispenses.

(11) A pharmacist shall provide pharmaceutical service:

(a) which is as complete as the public may reasonably expect;

(Rule 1140-2-.01, continued)

(b) without discriminating in any manner between patients or groups of patients; and

(c) without compromising the kind or extent of services or facilities made available.

(12) A pharmacist shall recognize the Tennessee Board of Pharmacy as the governing body of the practice of pharmacy in the State of Tennessee, and report to the board any violations of pharmacy laws or rules which may come to the pharmacists attention. The pharmacist at all times shall refrain from discussing these matters with nonmembers of the profession.

(13) The following functions must be performed personally by a pharmacist or by a pharmacy intern under the personal supervision and in the presence of a pharmacist:

(a) Certification of medical and prescription orders;

(b) Performance of final verification of the product prior to dispensing;

(c) Initialing of medical and prescription orders noting appropriate comments;

(d) Providing patient counseling;

(e) Proving direct patient care services;

(f) Providing drug information to patients, care givers, and health care providers;

(g) Supervision of compounding;

(h) Evaluation and establishment of criteria for selection of drug product(s) and supplier(s); and

(i) Daily opening and closing of a pharmacy practice site.

(14) A pharmacist and pharmacy intern shall wear appropriate identification showing name and appropriate title.

(15) A pharmacist shall immediately notify the board office in writing of a change in location of primary practice site and permanent residence.

~~(16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the primary pharmacy practice site. Pharmacists shall possess at all times, while engaged in the practice of pharmacy, proof of a license.~~

(16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the pharmacist's primary practice site, unless it is an institutional pharmacy practice site, in which case, the pharmacist's license and certificate of registration shall be maintained at the site.

(17) A pharmacist convicted of any crime, including driving under the influence of alcohol or controlled substances, shall report such conviction to the board within ten (10) days of the conviction becoming final. For purposes of this reporting requirement, a conviction includes pretrial or judicial diversion.

(18) A pharmacist shall comply with lawful order(s) of the board.

Authority: *T.C.A. §63-10-304(b)(1) and (c), T.C.A. §§63-10-404(26),(27), and (29), 63-10-504(b)(1), and 63-10-504(b)(1)(C).* ***Administrative History:*** *Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-2-.02 PHARMACY TECHNICIANS.

~~(1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:~~

~~(a) Provide a statement of good moral character;~~

~~(b) Submit an affidavit from his employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment.)~~

~~(c) Submit the appropriate application fee as set in Rule 1140-1-.10 of the Rules of the Board of Pharmacy.~~

~~(2) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.~~

~~(3) A pharmacy technician may perform the following functions, but only in the presence of and under the supervision of a pharmacist:~~

~~(a) Accept a request from a patient to refill a medical or prescription order;~~

~~(b) Accept or request authorization for a refill of a medical or prescription order from a practitioner or a practitioner's agent;~~

~~(c) Prepare a label to be placed on the dispensing container;~~

~~(d) Obtain and enter patient or medical or prescription order data into the patient information system;~~

~~(e) Retrieve prescription drugs and devices and related materials from stock, count or measure prescription drugs and devices and related materials, and place the prescription drugs and devices and related materials in the dispensing container;~~

~~(f) Affix a label to a dispensing container;~~

~~(g) Assist in reconstituting of prescription drugs;~~

~~(h) Assist in compounding;~~

~~(i) Transmit pharmacist approved orders to suppliers;~~

~~(j) Place ancillary information on the dispensing container;~~

~~(k) Prepackage and label drugs and devices and related materials for future dispensing;~~

~~(l) Deliver drugs and devices and related materials provided an established procedure is followed to ensure proper and safe delivery;~~

~~(m) Issue drugs and devices and related materials to authorized persons when such are to be used for administration to an inpatient;~~

~~(n) Prepare unit dose carts for final review by a pharmacist;~~

~~(o) Order drugs and devices and related materials from suppliers according to established criteria; and~~

(Rule 1140-2-.02, continued)

~~(p) Retrieve and transport drugs and devices and related materials to and from approved areas.~~

~~(4) In addition to the functions contained in paragraph (2) above, certified pharmacy technicians may receive new, or transferred oral medical and prescription orders.~~

~~(5) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by the pharmacy technician.~~

~~(6) The actual working ratio of pharmacy technicians to pharmacists shall not be more than 2:1 in any pharmacy practice site; provided, however, that the ratio may be increased to a maximum of 3:1 if at least one (1) of the pharmacy technicians is a certified pharmacy technician. For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.~~

~~(7) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g., pharmacy technician, certified pharmacy technician).~~

~~(8) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions. Supervision requires the physical presence of the pharmacist making appropriate in-process and end-process verifications of the pharmacy technician's activities.~~

~~(9) All registered technicians shall conspicuously display the technician's registration certificate at the primary practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.~~

~~(10) All registered technicians shall immediately notify the board in writing of any change of address or employer.~~

(1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:

(a) Provide a statement of good moral character;

(b) Submit an affidavit from his/her employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment);

(c) Submit the appropriate application fee as set in Board of Pharmacy Rule 1140-01-.10.

(2) The following individuals are exempt from registration as a pharmacy technician:

(a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.

(b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.

(3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.

(Rule 1140-2-.02, continued)

(4) A registered pharmacy technician may, in the presence of and under the supervision of a pharmacist, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.

(5) Certified pharmacy technicians may also:

(a) Receive new or transferred oral medical and prescription orders;

(b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and

(c) Verify the contents of unit dose carts prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.

(6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.

(7) Pharmacy Technician to Pharmacist Ratio

(a) The pharmacy technician to pharmacist ratio shall not exceed 2:1; however the ratio may be increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only if the additional pharmacy technicians are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:

1. the pharmacy technician's experience, skill, knowledge and training; and

2. the workload at the practice site; and

3. detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and

4. justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.

(b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

(8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).

(9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.

(10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.

(Rule 1140-2-.02, continued)

(11) All registered technicians shall immediately notify the board in writing of any change of address or employer.

(12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.

Authority: *T.C.A. §§ 63-10-304(b)(1), (e), and (j) and 63-10-306, T.C.A. §§63-10-404(30), 63-10504(b)(1), 63-10-504(b)(1)(C), 63-10-506, and 63-10-508.* ***Administrative History:*** *Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002*